



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Rajesh MANCHANDA et al.

Confirmation No.: 9728

Serial No.: 09/855,542

Examiner: Shahnam J. Sharareh

Filed: May 16, 2001

Group Art 1617
Unit:

Title: STABILIZATION OF RADIONUCLIDE-CONTAINING COMPOSITIONS

RESPONSE TO REQUIREMENT FOR RESTRICTION AND ELECTION OF SPECIES

MAIL STOP NON-FEE AMENDMENT

Commissioner for Patents

Box 1450

Alexandria, Virginia 22313-1450

SIR:

This is in response to the Office Action mailed May 23, 2005. In response to the restriction requirement set forth therein, Applicants hereby elect Group I, claims 1-4, 6-10 and 32-33, drawn to the compositions. Further, in response to the election of species requirement therein, applicants hereby elect the species wherein the composition comprises: 1) Tc-99m as the radionuclide, 2) a peptide, particularly depreotide (i.e., cyclo-(M-Me)Phe-Tyr-(D)Trp-Lys-Val-Hcy(CH₂COO-β-Dap-Lys-Cys-Lys-NH₂), as the targeting agent and 3) iodide ions. It is believed that claims 1-4, 8-10 and 32-33 encompass the elected species. The restriction and election of species elections are both made with traverse for the reasons set forth below. Applicants reserve the right to file one of more divisional applications directed to the non-elected subject matter.

The restriction requirement is traversed on the grounds that full examination and prosecution of both restricted groups together has already occurred in this application. Five full

Office Actions on the merits and one Advisory Action have already been issued in the prosecution of this application wherein no restriction was made between the current types of composition and method claims. Because the composition and method claims have already been fully searched and examined together by the USPTO on numerous occasions, it is not seen how a continuation of the prosecution on the compositions and methods together could be a serious burden of extra search and examination on the Examiner. Additionally, it is believed an absence of serious burden is further evidenced by the eventual need to rejoin the method claims anyway. Because the method claims should, eventually, be rejoined, no added burden is seen in including them in the examination now. In the absence of a serious burden, restriction is not proper. Applicants understand that most of the prior prosecution was conducted by a different Examiner. However, applicants submit that a change in Examiner does not justify modification of the prosecution in a manner which is inconsistent with the Office's own rules (i.e., a serious burden is required to justify restriction).

The election of species requirement is traversed for similar reasons as above. A significant amount of prosecution has already occurred. In fact, at the beginning of the prosecution, applicants already made the same election of species as is made above. No need for repetition of the requirement is apparent. In any event, the Examiner is encouraged to examine the broadest possible scope of invention indicated by the elected species. In accordance with M.P.E.P. §803.02, the Examiner is reminded that, should no prior art be found which renders the invention of the elected species unpatentable, the search of the remainder of the generic claim(s) should be continued in the same application. It is improper for the PTO to refuse to examine in one application the entire scope of the claims therein unless they lack unity of invention. The

generic claims herein have not been alleged to lack unity of invention.

Favorable action is earnestly solicited.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John A. Sopp", is written over a horizontal line.

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